

## REMARKS

There are several errors in the first action Detailed Action presented by the examiner in paper 11, mailed September 24, 2002. Among them is an incorrect opinion that this first action could qualify as a final action, which is incorrect because of factual errors in the reasoning presented in the action. Among these is included that compositional claims can anticipate a method invention using totally different steps than described in the prior art.

First the 35 USC §112 rejection reasoning is factually incorrect. The originally filed application, "the 7/21/00 application", has the exact wording in the case "to prevent collapse of said follicle during release of said compound/drug" stated by the examiner as "new". As is stated on page 5, lines 24-26 of the 7/21/00 Application, the text explicitly states that the swellable compositions maintain a passage for delivery of desired compounds by "either opening hair follicles and preventing them from collapsing . . ." Maintaining a passage for the desired compounds necessarily requires that this happen during release of the compound. This is reinforced in Example 1 on page 7, lines 24-25. Since the exact words were in the original specification they can not be considered new matter now, just because they are introduced into a claim.

The second set of words, "with an intact stratum corneum", which the examiner is stating is new matter, is also an incorrect analysis, especially when taken in the context of those skilled in the art of the present invention, namely, dermatologists, skin care professionals, persons developing topical delivery systems for drugs or cosmetics, and generally persons knowledgeable in the physics and properties of skin. Furthermore, anyone familiar with skin or who views Fig. 1 and reads the explanation on page 7 (original 7/21/00 application) lines 9-19, understands that "skin" is a multilayered structure with the (outermost) superficial layer being the stratum corneum. The barrier properties of the stratum corneum are well known, to those skilled in the art, and are pointed out in several areas throughout the originally filed application. Those who work with materials which need to penetrate this barrier understand that a wound or other breach in the continuum of the stratum corneum changes dramatically the penetration. This is to say that stating an objective of the present invention as, "to provide topical compositions for opening hair follicles to enhance compound/drug penetration in the skin without stratum corneum modification . . .", as done on page 5 lines 10-12 (original 7/21/00 application), is equivalent to defining "an

intact stratum corneum" being present. Further evidence is seen on page 8 of the 7/21/00 Application in its description of Example 1. The first step in this example involves topically applying the composition "on the skin areas where compound/drug penetration is desired . . . ." Skin is defined on the previous page of the 7/21/00 Application. As is mentioned above and described on page 7, "skin comprises 4 principal layers. The superficial region of the skin (first layer) is stratum corneum . . . ." It is evident that the skin as described in the specification of the 7/21/00 Application would be intact, and therefore must inherently have an intact stratum corneum. Nowhere is it described to somehow break the stratum corneum, so it must be intact. The specification clearly contemplated use of the present invention on skin with an intact stratum corneum. Simply stating "intact" as a shorthand for the fuller description does not introduce new matter. But the inclusion of this 'limitation' may not be critical to differentiation from the prior art presented by the examiner as detailed below.

In simple language, the present invention deals with a Method/process to enhance transmission of compounds through a normal (healthy) human/animal skin without providing new paths through the barrier layer found in normal skin as for example done by Neuberger in US 6,355,054. The method can be done in conjunction with an epilation or independently. There are no device or composition claims. The Suzuki et al. patent (US 4,292,299) claims to be a medical preparation, which in effect defines a type of adherent polymeric 'patch delivery system' for the slow release of the medical preparation to a wet mucous surface. Schaefer et al. in US 5,292,512 also claims to be a composition, cosmetic or pharmaceutical in nature, for topical applications.

Neither deals with process or method claims.

Suzuki et al. teaches a bandage material which is swellable. When the material of the bandage swells it exudes or pushes out a drug/medicament within the bandage into the wound to help cure. Alternatively, the drug/medicament may lie in a dissolvable layer between the swellable material and the wound. Here as the swellable layers press on the medicated, non-swellable layer, the latter is forced closer to the wound surface and the drug/medicament is again driven towards the wound surface. In either case, an external material (bandage) containing some drug/medicament is wrapped over a wound, (wet mucous surface of a mucous membrane or skin). The bandage is then swollen and overtime the slow release of the drug/medicament from the swollen bandage occurs. To achieve this the drug/medicament must be excluded from the swelling material slowly. This occurs if the swelling is slow or the exclusion of the drug/medicament is slow from the swellable material.

In sharp contrast, the present invention applies material which enters the hair follicles, either before or after epilation, and is swollen within the hair follicle to maintain an opening for the passage of drug/medicaments into the epidermis, dermis and beyond. The material of the present invention does nothing on the surface of the skin, but is designed to infiltrate the stratum corneum of intact skin to provide an enhanced pathway for compounds to penetrate the stratum corneum. In a preferred embodiment the swellable material contains the drug/medicament within smaller particles which can be released by chemical, thermal, radiation, or other means after the swellable particles have entered hair follicles and opened or maintained open the follicles. The drug/medicament/compound then enters the epidermis or dermis by passing through the walls of the follicle. There is no external device (bandage) to bring the swellable material or drug/medicament/compound to the skin. The stratum corneum is continuous with the exception of its naturally occurring pores. The swellable material is swollen within the confines of the hair follicles (pores) not outside the skin. The swellable material releases the compound/drug immediately on demand within the present invention. This may be delayed in time after swelling is accomplished, but it equates to a slow release process. Neither the composition claims nor specification of Suzuki et al. teach or make obvious the present Method/Process invention.

Schaefer et al., as noted above, is another composition invention. It deals with a structure for a cosmetic or pharmaceutical composition based on microspheres having a specific range of diameters. It does not deal with or teach anything about collapsing hair follicles or how to prevent this from happening. It deals primarily with size restrictions for particles which can carry active substances into a hair follicle. It does not instruct or imply anything about using a swelling process. It does not anticipate nor make obvious the method/process claims of the present invention.

The examiner claims it possible to combine the teachings of Suzuki et al. and Schaefer et al. to make obvious the Method/Process claims of the present invention. It is hard to conceive how one skilled in the art of trying to penetrate the stratum corneum barrier or one involved with accomplishing a systemic application of a compound/drug alternatively to oral ingestion would look to a swellable, adherent bandage invention to advance the art of getting compounds through a human/animal skin. There is no direct reason for combining these inventions without the hindsight of reading about the present invention. For the above reasons, the present invention is not obvious over Suzuki et al. in view of Schaefer et al.

With these remarks it is believed that the disclosure should undergo the full examination warranted for this RCE and further that it is now in condition for allowance. Reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Respectfully submitted,

Dated: December 18, 2002

A handwritten signature in black ink, appearing to read "Bolesh J. Skutnik". The signature is fluid and cursive, with the first name "Bolesh" and last name "Skutnik" clearly distinguishable.

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